

(2) A statement that the approval has been granted for a proprietary formula and/or specifications.

(f) *When is a medicated feed mill license required for the manufacture of a free-choice medicated feed?* An approved medicated feed mill license is required for the manufacture of the following types of feeds:

(1) All free-choice medicated feeds that contain a Category II drug, and

(2) Free-choice medicated feeds that contain a Category I drug and use a proprietary formula and/or specifications.

[69 FR 30197, May 27, 2004]

Subpart F—Animal Use Exemptions From Certification and Labeling Requirements

§ 510.515 Animal feeds bearing or containing new animal drugs subject to the provisions of section 512(n) of the act.

Animal feeds that bear or contain penicillin, chlortetracycline, feed grade zinc bacitracin, and bacitracin methylene disalicylate, with or without added suitable nutritive ingredients are exempt from the certification requirements of section 512 of the act provided they are the subject of and in compliance with regulations for their use in this subchapter E, part 558 of this chapter, or any one of the paragraphs of this section:

(a) Where indicated in paragraph (b) of this section it is manufactured with or without one, but only one, of the following ingredients in a quantity, by

weight of feed, as hereinafter indicated:

(1) Arsanilic acid: Not less than 0.005 percent and not more than 0.01 percent.

(2) Sodium arsanilate: Not less than 0.005 percent and not more than 0.01 percent.

(3) 3-Nitro-4-hydroxyphenylarsonic acid: Not less than 0.0025 percent and not more than 0.0075 percent except in chicken or turkey feed which shall contain not less than 0.0025 percent and not more than 0.005 percent.

(b) It is intended for use in any one of the following conditions set forth in this paragraph:

(1) It is intended for use solely in the treatment of chronic respiratory disease (air-sac infection), infectious sinusitis, and blue comb (nonspecific infectious enteritis) in poultry and/or bacterial swine enteritis; its labeling bears adequate directions and warnings for such use; and it contains, per ton of feed, the equivalent of 100 grams of penicillin. When intended for uses specified in this paragraph, it may also contain, in the amount specified, one, but only one, of the ingredients prescribed by paragraph (a) of this section.

(2) It is intended for use solely in the treatment of chronic respiratory disease (air-sac infection) and infectious sinusitis in poultry; its labeling bears adequate directions and warnings for such use; and it contains not less than 0.1 percent para-aminobenzoic acid or the sodium or potassium salt or para-aminobenzoic acid.

(3)–(29) [Reserved]

(c) It is intended for use as follows:

Product	Species	Use levels	Indications for use
1. Nicarbazin	Chickens	0.01 to 0.02 percent	For use in the prevention of outbreaks of coccidiosis in poultry flocks; growth promotion and feed efficiency.
.....dodo	2.4 to 50 g/ton	
2. Nicarbazindo	0.01 to 0.02 percent	Do.
Bacitracin methylene disalicylate.do	4 to 50 g/ton.	
3. Nicarbazindo	0.01 to 0.02 percent	For use as an aid in the prevention of coccidiosis in poultry flocks; growth promotion and feed efficiency; improving pigmentation.
Bacitracin methylene disalicylate.do	4 to 50 g/ton.	
3-Nitro-4-hydroxyphenylarsonic acid.do	0.0025 to 0.005 percent.	
4. Nicarbazindo	0.01 to 0.02 percent	Do.
Procaine penicillindo	2.4 to 50 g/ton.	
3-Nitro-4-hydroxyphenylarsonic acid.do	0.0025 to 0.005 percent.	

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Product	Species	Use levels	Indications for use
5. Chlortetracycline	Swine	10 to 50 g/ton	Enhancement of growth and feed efficiency.
Arsanilic aciddo	0.005 to 0.01 percent.	

[41 FR 8299, Feb. 25, 1976, as amended at 41 FR 11011, Mar. 15, 1976; 42 FR 18614, Apr. 8, 1977; 47 FR 42102, Sept. 24, 1982; 47 FR 51563, Nov. 16, 1982; 56 FR 41912, Aug. 23, 1991; 58 FR 30119, May 26, 1993; 61 FR 35950, July 9, 1996]

Subpart G—Sponsors of Approved Applications

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

(a) Section 512(i) of the act requires publication of names and addresses of sponsors of approved applications for new animal drugs.

(b) In this section each name and address is identified by a numerical drug labeler code. The labeler codes identify the sponsors of the new animal drug applications associated with the regulations published pursuant to section 512(i) of the act. The codes appear in the appropriate regulations and serve as a reference to the names and addresses listed in this section. The drug labeler code is established pursuant to section 510 of the act.

(c) The names, addresses, and drug labeler codes of sponsors of approved new animal drug applications are as follows:

(1) ALPHABETICAL LISTING OF SPONSORS

Firm name and address	Drug labeler code
Abbott Laboratories, North Chicago, IL 60064 ...	000074
ADM Alliance Nutrition, Inc., 1000 North 30th St., Quincy, IL 62305-3115	021930
ADM Animal Health & Nutrition Division, 1000 North 30th St., Box 1C, Quincy, IL 62305-3115	017519
Ag-Mark, Inc., P.O. Box 127, Teachey, NC 28464	024174
Agri Laboratories, Ltd., P.O. Box 3103, St. Joseph, MO 64503	057561
Agri-Tech, Inc., 4722 Broadway, Kansas City, MO 64112	017762
Akzo Nobel Surface Chemistry AB, Box 851, S-44485 Stenungsund, Sweden	063765
Alaco, Inc., 1500 North Wilmot Rd., suite 290-C, Tucson, AZ 85712	064146
Alpha Inc., One Executive Drive, Fort Lee, NJ 07024	046573
Alstoe, Ltd., Animal Health, Pera Innovation Park, Nottingham Rd., Melton Mowbray, Leicestershire, England LE13 0PB	062408
Altana Inc., 60 Baylis Rd., Melville, NY 11747 ...	025463

(1) ALPHABETICAL LISTING OF SPONSORS—Continued

Firm name and address	Drug labeler code
American Pharmaceuticals Partners, Inc., 2045 North Cornell Ave., Melrose Park, IL 60160 ...	063323
Anika Therapeutics Inc., 236 West Cummings Park, Woburn, MA 01801	060865
Animal Health Pharmaceuticals, LLC, 1805 Oak Ridge Circle, suite 101, St. Joseph, MO 64506	068718
Argent Laboratories, 8702 152d Ave. NE., Redmond, WA 98052	051212
Ausa International, Inc., Rt. 8, P.O. Box 324-12, Tyler, TX 75703	059521
Baxter Healthcare Corp., 95 Spring St., New Providence, NJ 07974	010019
Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201 ...	000859
Bertek Pharmaceuticals, Inc., 12720 Dairy Ashford, Sugar Land, TX 77478	062794
Biocraft Laboratories, Inc., 92 Route 46, Elmwood Park, NJ 07407	000332
Bioniche Animal Health USA, Inc., 119 Rowe Rd., Athens, GA 30601	064847
Bioproducts, Inc., 320 Springside Dr., Suite 300, Fairlawn, OH 44333-2435	051359
Biopure Corp., 11 Hurley St., Cambridge, MA 02141	063075
BioScience Division of Milk Specialties Co., 1902 Tennyson Lane, Madison, WI 53704	032761
Boehringer Ingelheim Vetmedica, Inc., 2621 North Belt Highway, St. Joseph, MO 64506-2002	000010
Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, County Galway, Ireland	061651
Church & Dwight Co., Inc., 469 North Harrison St., Princeton, NJ 08543-5297	010237
ConAgra Pet Products Co., 3902 Leavenworth St., Omaha, NE 68105	021091
Contemporary Products, Inc., 3788 Elm Springs Rd., Springdale, AR 72764-6067	055462
Cooperative Research Farms, Box 69, Charlotteville, NY 12036	051267
Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland	061623
Custom Feed Blenders Corp., 540 Hawkeye Ave., Fort Dodge, IA 50501	046987
Custom Feed Services Corp., 2100 N. 13th St., Norfolk, NE 68701	017473
ECO LLC, 8209 Hollister Ave., Las Vegas, NV 89131	066916
Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285	000986
Endo Pharmaceuticals, Inc., 100 Painters Dr., Chadds Ford, PA 19317	060951
Eon Labs Manufacturing, Inc. 227-15 North Conduit Ave., Laurelton, NY 11413	000185
Evsco Pharmaceuticals, An Affiliate of IGI, Inc., Box 209, Harding Hwy., Buena, NJ 08310	017030